PHARMACEUTICAL & LABORATORY · GUIDE

The skills matrix *for pharma labs*

In a regulated lab, an analyst may not perform a test independently until they are qualified on that specific validated method, and that qualification must be current and on record for inspection. A skills matrix maps every method against who is qualified to run it, so a QC manager can see which methods have dependable cover, which rest on a single analyst, and which qualifications are due for reassessment, before an OOS investigation or an auditor finds the gap.

Dr Alex J. Martin-Smith
CMGR · MBA · LLM · DBA

Reading time 12 min · **Method** Upleashed 0 to 5 capability framework · **Updated** May 2026

THE SHORT ANSWER

A pharmaceutical or laboratory skills matrix maps analysts against the specific validated methods and competencies they must be qualified on, scored on a clear scale, with qualification and reassessment status tracked. Read it method by method: which have dependable qualified cover, which rest on one analyst, and which qualifications are lapsing. In short: **it shows method-level qualified cover against GxP requirements, so single-analyst methods, lapsing competencies and training gaps surface before an out-of-specification result or an inspection exposes them.**

KEY TAKEAWAYS

- **Qualification is method-specific.** An analyst must be qualified on the exact validated method, not just generally trained, before testing independently.
- **Map to the method, not the role.** Columns are validated methods and techniques, HPLC, sterility, dissolution, each qualified separately.
- **Competency must be maintained.** GxP requires ongoing qualification and reassessment, so the matrix tracks currency, not just initial sign-off.
- **Single-analyst methods are critical risk.** A regulated method one analyst can run is a continuity and compliance exposure.
- **Records must be inspection-ready.** Training and qualification evidence is required to be retained and reviewable; the matrix keeps it current.

START HERE

Qualified on the *method*

In a GxP laboratory, capability is defined at the level of the **validated method**. Being a skilled analyst in general is not enough; under the regulations an analyst may not perform a given test independently until they are trained and qualified on that specific method, and cannot resume it after an error until requalified. That makes a lab skills matrix method-specific by necessity: it maps who is qualified on what, exactly, and whether that qualification still holds.

Map methods, not just roles

The columns of a lab matrix are the **validated methods and techniques** the lab runs, HPLC assay, dissolution, titration, sterility, bioburden, endotoxin, stability testing, organised by section. Each is qualified separately, because competence on one says nothing about another: an analyst signed off on HPLC is not thereby qualified on a microbiological method. Mapping at this granularity is what turns the matrix into an accurate picture of which methods the lab can actually run, and by whom.

Track qualification and reassessment

GxP does not treat qualification as a one-off. Personnel must be **trained, qualified and remain competent**, with ongoing reassessment and refresher training on a defined cycle, and effectiveness evaluated, not just attendance logged. So the matrix tracks currency: when each analyst was qualified on a

method, when reassessment is due, and where a competency has lapsed. A qualification that has expired removes that analyst as valid cover for the method until requalified, exactly as a regulator would expect.

Find single-analyst methods and gaps

The risks a lab matrix most needs to surface are **single-analyst methods and qualification gaps**. A validated method only one analyst is qualified to run is a serious exposure: if they are absent or leave, testing stalls and turnaround slips, with regulatory and supply consequences. By showing qualified cover method by method, the matrix flags these single points of failure and the methods where qualification is thin, so the lab can train a second analyst and close gaps before they disrupt testing or surface in an audit.

WHY IT MATTERS NOW

Unqualified means *the test waits*

In a regulated lab, only a qualified analyst may run a method, so a single-analyst method or a lapsed qualification directly threatens testing, turnaround and compliance. Mapping method-level qualification is how a QC lab stays both productive and inspection-ready.

8%

GARTNER, 2024

of organisations have reliable workforce skills data, so most labs track qualification in scattered training files.

21 CFR 211.25

FDA

requires personnel to be trained and qualified for their tasks, with records retained for inspection and review.

63%

WEF, 2025

of employers call skills gaps the biggest barrier to change; in a QC lab they read as methods that cannot be run.

A QC laboratory operates under a hard constraint: regulators require that each person be qualified to perform the functions assigned to them and remain competent, with that evidence retained and reviewable. Fall short, through a single-analyst method, a lapsed reassessment, an analyst running

a test they are not signed off on, and the lab risks delayed testing, invalidated results, observations at inspection, or worse. A skills matrix is the instrument that holds this together. It maps **qualification at method level** against the lab's full portfolio, shows where cover is thin or resting on one analyst, tracks when reassessment falls due, and keeps the qualification evidence current and inspection-ready. Run this way, the lab can schedule testing with confidence, train deliberately against real gaps, and demonstrate compliant, competent staffing on demand rather than reconstructing it under audit pressure.

WHAT IT PROTECTS

Four things a pharma lab matrix safeguards

In a regulated laboratory, a skills matrix protects four things that bear directly on compliance, quality and testing throughput. Each follows from mapping qualification at the level of the method.

PROTECTS 01

Testing continuity

By revealing single-analyst methods, the matrix lets you train backup before an absence stalls a test and delays release.

PROTECTS 02

Qualification currency

It flags reassessments and refreshers falling due, so competency stays current and no analyst runs a method on a lapsed sign-off.

PROTECTS 03

Data integrity & quality

It ensures only analysts qualified on a method run it, the basis of reliable results and sound out-of-specification handling.

PROTECTS 04

Inspection readiness

It keeps method-level qualification evidence current and to hand, ready for the records regulators require to review.

The common thread is **compliant capability you can prove**. A regulated lab cannot simply believe its analysts are competent; it must qualify them method by method, keep them current, and show the evidence on demand. Capability here is distributed across a portfolio of validated methods, each requiring specific qualification, and scrutinised by inspectors who expect retained records. The matrix makes that picture visible and current, so the lab can run testing without interruption, keep every qualification in date, uphold

data integrity, and meet an inspection with its competency evidence already in order.

THE SCALE BEHIND THE SCORES

The 0 to 5 capability framework

A regulated lab needs a scale that maps onto qualification status, distinguishing an analyst in training from one signed off to test independently, and marking those who can train and assess others. This framework, developed by Dr Alex J. Martin-Smith, does that, with Level 3, qualified to run the method unsupervised, as the bar for counting as cover.

0

Not required for the role

EXCLUDED

The method is not part of this analyst's role. Excluded from the score, keeping the matrix focused on the methods each person is expected to be qualified on.

1

In training

WEIGHTING 25%

Undergoing training on the method, works under direct supervision. Up to 75% trained. Not yet qualified to perform the test independently or sign results.

2

Supervised / Developing

WEIGHTING 50%

More than 75% trained; can run routine analyses with oversight, but not yet fully qualified for independent testing. Approaching sign-off on the method.

3

Qualified

WEIGHTING 75% · COUNTS AS COVER

Formally qualified to perform the validated method unsupervised and report results. The level that counts as genuine cover, provided the qualification is current.

4

Trainer / Assessor

WEIGHTING 100%

Deep method expertise; trains and assesses other analysts, investigates complex results and OOS. The people who qualify others and reduce single-analyst risk.

5

Method / Section owner

WEIGHTING 100%

Owns the method or section, its validation, SOPs and standards. The subject expert accountable for how the method is run and maintained across the lab.

Count current, qualified cover per method

For each validated method, count the analysts at Level 3 or above whose qualification is **current**, that is your dependable cover. A method with only one qualified analyst is a **single point of failure**; one where qualifications are lapsing is a compliance gap forming. A lapsed reassessment drops an analyst out of cover for that method until requalified, regardless of experience. The weightings let you express each method's and section's overall capability for trend reporting and gap analysis.

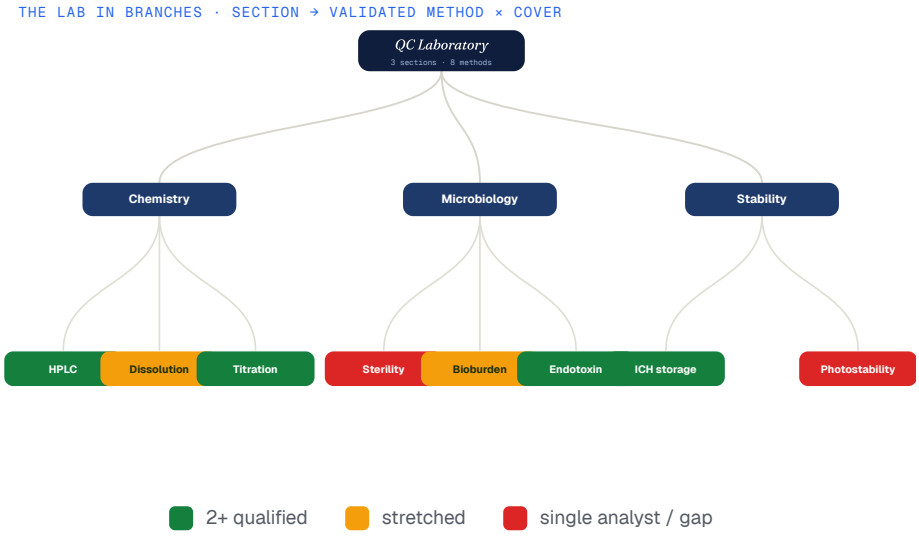
A worked example. Same lab, very different method risk:

```
HPLC assay  4 analysts qualified and current  →  dependable
cover
Sterility  1 qualified analyst  →  single point of failure
both are validated and critical — sterility is the priority
to build backup on.
```

SEE THE LAB

The lab, *method by method*

Here is the laboratory as a tree: the lab branches into its sections, and each section into the validated methods it runs, with every method coloured by how well it is covered, green for dependable qualified cover, amber for stretched, red for a single analyst or a gap. Following a branch to a red method shows exactly where the lab is exposed, and in which section to act.



Sterility & photostability

rest on a single analyst, regulated methods with no backup, the priority to qualify a second analyst on

Illustrative QC lab on the Upleashed 0 to 5 framework. The lab branches to sections then validated methods; colour shows current qualified cover per method.

WHAT THE QC MANAGER READS HERE

- **Two red methods stand out.** Sterility in microbiology and photostability in stability each rest on a single qualified analyst. Both are validated, critical methods, qualifying a second analyst on each is the highest-priority action.
- **Amber methods are stretched.** Dissolution and bioburden are holding but thin. Worth building cover or scheduling reassessment before they slip to a single-analyst position.
- **Read the tree by section.** Microbiology carries the most exposure (a red and an amber), so it is the section to focus development and recruitment on first, rather than spreading effort evenly.
- **Green methods are the model.** HPLC, titration, endotoxin and ICH storage show dependable cover. Resilient, inspection-ready, and the pattern to bring the red and amber methods up to.

READY-TO-USE EXAMPLES

Example areas to map for a pharma lab

A pharmaceutical or laboratory matrix should map analysts against the validated methods, instrumentation and regulatory competencies the lab depends on. Here are ready-to-adapt categories, a starting point to tailor to your lab.

Category	Examples to map (the columns)	Watch out for
Analytical methods	HPLC assay, dissolution, titration, GC, spectroscopy, related substances	A critical assay only one analyst is qualified to run
Microbiology	Sterility, bioburden, endotoxin, environmental monitoring, identification	Thin cover on sterility, where the consequences are severe
Stability	ICH storage, photostability, stability-indicating methods, trending	Long-running studies stalling if the qualified analyst leaves
Quality & compliance	GMP / GxP, data integrity, OOS investigation, deviation handling	Mapping technique but missing the compliance competencies
Instrument & systems	Calibration, qualification, LIMS / chromatography data systems	Assuming method skill implies the systems and data-integrity skill

Map analysts against the specific validated methods and competencies the lab runs, scored so Level 3 means formally qualified to perform the method unsupervised, and track qualification and reassessment dates alongside the level. Keep the compliance competencies, data integrity, OOS, GxP, in view, since gaps there expose the lab regardless of analytical strength. As always, map at method granularity, keep qualifications current, and use the picture to build backup on single-analyst methods and target training where it most reduces risk.

AVOID THESE

Six mistakes on a pharma lab matrix

MISTAKE 01

Mapping the role, not the method

General training is not method qualification. Map each validated method separately.

MISTAKE 02

Ignoring currency

A lapsed reassessment is no cover. Track when qualification and refreshers fall due.

MISTAKE 03

Single-analyst methods

One qualified analyst on a critical method is fragile. Qualify a second before an absence stalls testing.

MISTAKE 04

Skipping compliance skills

Data integrity and OOS handling are core. Map them, not just analytical technique.

MISTAKE 05

Logging attendance, not competence

A signed training sheet is not proven competence. Assess and record actual qualification.

MISTAKE 06

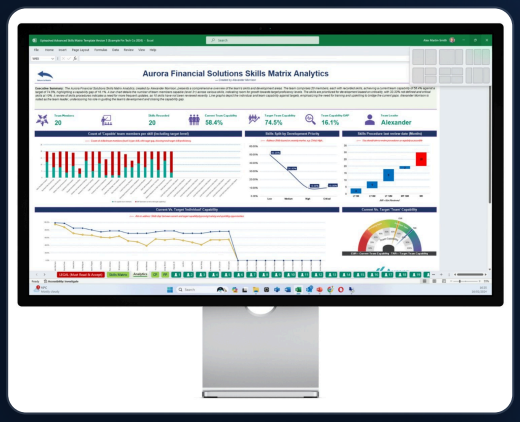
Records not inspection-ready

Regulators require retained evidence. Keep method-level qualification current and to hand.

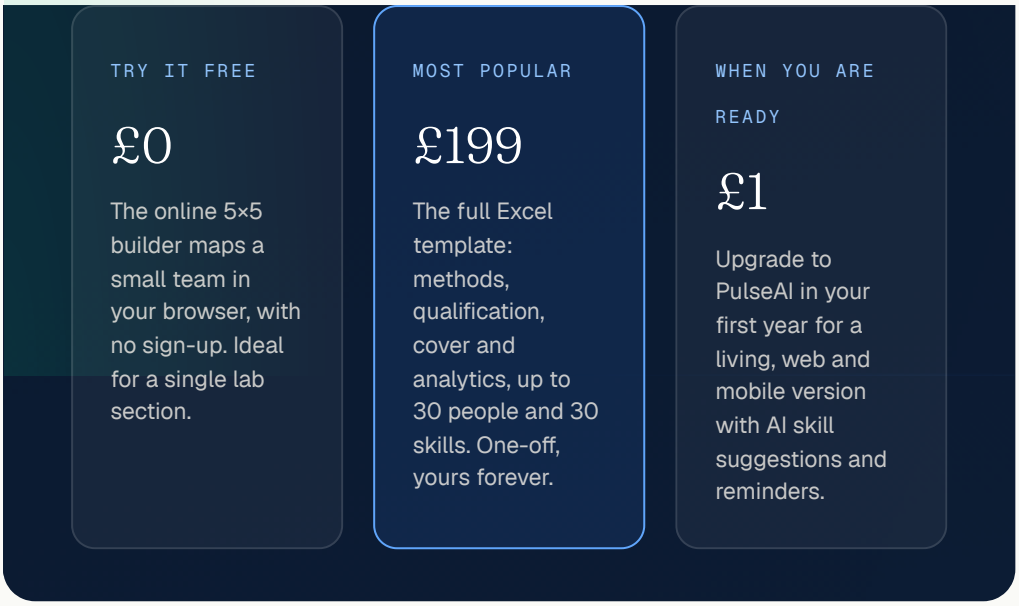
FROM SCATTERED TRAINING FILES TO METHOD-LEVEL PROOF

The method is free. A ready-made matrix just makes the single-analyst methods and lapsing qualifications *impossible to miss.*

Everything here works in a blank spreadsheet, and that is a fine place to start. A purpose-built template just makes the lab view effortless: map analysts on the 0 to 5 scale across every validated method, track qualification and reassessment dates, and the current qualified cover per method is counted for you, so the single-analyst methods, the lapsing competencies and the training gaps stand out, and the evidence is ready when an inspector asks.



The Advanced Excel Skills Matrix counts current qualified cover per validated method, the basis for protecting testing continuity, maintaining qualification and staying inspection-ready, all on the same 0 to 5 framework used throughout this guide.



COMMON QUESTIONS

Quick *answers*

Q What is a skills matrix for a pharmaceutical lab?

It is a grid mapping analysts against the specific validated methods and competencies the lab runs, with a qualification level in each cell and reassessment status tracked. Read method by method, it shows which methods have dependable qualified cover, which rest on a single analyst, and where qualifications are lapsing, against GxP requirements.

Q Why map at method level rather than by role?

Because GxP qualification is method-specific: an analyst must be qualified on the exact validated method before performing it independently, and competence on one method does not transfer to another. Mapping each method separately is the only way to know accurately which tests the lab can run, and by whom, which a role-level view obscures.

Q Why track reassessment and currency?

Because regulations require personnel to remain competent, not just to have been trained once, with ongoing reassessment and refresher training on a defined cycle. A qualification that has lapsed no longer provides valid cover for the method until renewed, so the matrix must track when each is due, exactly as an inspector would expect.

Q How does it reduce single points of failure?

By showing qualified cover for each validated method. A method only one analyst is qualified to run is a serious exposure, if they are absent or leave, that testing stops. The matrix flags these single-analyst methods so the lab can qualify a second analyst before an absence disrupts testing and delays product release.

Q How does it support inspection readiness?

Regulators such as the FDA and EMA require training and qualification records to be retained and available for review. A skills matrix keeps method-level qualification and reassessment evidence current and in one place, so competency can be demonstrated on demand, rather than reconstructed under the pressure of an announced inspection.

Q Does this suit other regulated labs?

Yes. While framed for pharmaceutical QC, the same method-level, qualification-tracking approach suits any regulated or accredited laboratory, clinical, food, environmental, materials. Wherever analysts must be qualified on specific validated methods and competency must be maintained and evidenced, mapping qualification by method keeps the lab compliant and its testing resilient.

ABOUT THE AUTHOR

Dr Alex J. Martin-Smith

CMGR · MBA · LLM · DBA

Alex is the creator of the Upleashed capability framework that powers Skills Matrix Template, the award-winning Excel skills matrix. A Chartered Manager with an MBA, an LLM and a doctorate in business administration, he has spent more than two decades helping operations, HR and quality teams turn capability from a gut feel into something they can measure, manage and prove.

Connect on LinkedIn: linkedin.com/in/alexmartinsmith

Dr Alex J. Martin-Smith

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Qualify the method, *not just the analyst.*

You now have the pharma lab method. The quickest way to start is to list your validated methods, mark who is qualified and current on each, and follow the branches to the red ones. The single-analyst methods and lapsing qualifications you find are exactly where to build backup and book reassessment, before a test stalls or an auditor asks.

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